

Proposed Patient Information Leaflet

SCHEDULING STATUS

S2

MEDAZINE S (12,5 mg Syrup).

cyclizine hydrochloride

Contains sorbitol 70 %

Contains sugar (Liquid glucose 1,25 mg and sucrose 0,5 mg per 5 mL)

Contains sweetener (saccharine sodium 2,5 mg per 5 mL)

Read all of this leaflet carefully because it contains important information for you

MEDAZINE S is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use MEDAZINE S carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MEDAZINE S with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What MEDAZINE S is and what it is used for
2. What you need to know before you give MEDAZINE S
3. How to give MEDAZINE S
4. Possible side effects
5. How to store MEDAZINE S
6. Contents of the pack and other information

1. What MEDAZINE S is and what it is used for

The active substance in MEDAZINE S is cyclizine hydrochloride, which belongs to a group of medicines called antihistamines which can be used to help stop you feeling sick (nausea) or being sick (vomiting). MEDAZINE S can also be used to treat sickness caused by some inner ear problems such as Meniere's disease.

2. What you need to know before you give MEDAZINE S

Do not give MEDAZINE S:

- If your child is allergic (hypersensitive) to cyclizine or to any of the inactive ingredients of MEDAZINE S (listed in **section 6**), or if your child has previously suffered an adverse reaction to cyclizine.
- To a pregnant or breastfeeding mother, as safety has not been established (see **Pregnancy, breastfeeding and fertility**).
- If your child suffer from an acute asthma attack, as MEDAZINE S may worsen your child's condition.
- If your child has been diagnosed with a condition called narrow angle glaucoma [increased pressure inside the eye(s)].
- If your child has difficulty urinating.
- If your child has been diagnosed with enlargement of the prostate.
- If your child has been diagnosed with a condition called emphysema, or chronic lung disease.
- If your child suffer from shortness of breath or difficulty breathing.

Warnings and precautions

MEDAZINE S may lead to drowsiness and impaired concentration, which may be aggravated by simultaneously taking alcohol or certain other medicines, i.e. sleeping tablets or tranquillisers.

Special care should be taken with MEDAZINE S:

If your child suffer from any of the following conditions:

- Skin reactions.
- Liver disease.
- Epilepsy. If your child has suffer from epilepsy or previously suffered a fit or seizure, taking more MEDAZINE S than recommended may induce a fit/seizure.
- Heart failure.

MEDAZINE S may suppress positive skin test results.

Children and adolescents

In children MEDAZINE S may act as a brain stimulant and cause excitation. Possible symptoms include sleeplessness, nervousness, increased heart rate, tremors, muscle twitching and convulsions (seizures). If you or your child develops any of these symptoms, stop giving MEDAZINE S and report to your doctor.

Other medicines and MEDAZINE S

Always tell your health care provider if your child is taking any other medicine. (This includes all complementary or traditional medicines).

MEDAZINE S may enhance the effects of the following:

- Barbiturates such as phenobarbital (medicines used to treat pain which may cause sedation).
- Hypnotics, medicines used to assist with difficulty sleeping and anxiety.
- Anticholinergic medicines such as atropine.
- Antidepressants such as amitriptyline.
- Pethidine (used in the management of pain).

- Medicines which fall under a class called monoamine oxidase inhibitors such as Tranylcypromine.

MEDAZINE S with food and, drink and alcohol

Alcohol should be avoided when taking MEDAZINE S, as it may increase the effects of alcohol.

Pregnancy, breastfeeding and fertility

The safety of MEDAZINE S in pregnancy and breastfeeding mothers has not been established.

Driving and using machines

MEDAZINE S may cause increasing drowsiness and decreased concentration, especially when taken with alcohol and other medicines, e.g. sleeping tablets and tranquillisers. Your child must not drive or operate machinery or perform other hazardous tasks if they have taken MEDAZINE S. (see **Warnings and precautions**).

3. How to take MEDAZINE S

Do not share medicines prescribed for your child with any other person.

Always give MEDAZINE S exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Children 6 to 12 years

Give 10 mL (2 medicine measures), may be repeated up to three times daily.

Children 1 to 5 years

Give 5 mL (1 medicine measure), may be repeated up to three times daily.

Motion sickness

For the prevention of motion sickness, MEDAZINE S Syrup should be taken about half an hour before the journey.

If you take more MEDAZINE S than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take use MEDAZINE S

Just take the next dose at the usual time, Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MEDAZINE S can have side-effects.

Not all side-effects reported for MEDAZINE S are included in this leaflet. Should your child general health worsen or if your child experience any untoward effects while taking MEDAZINE S, please consult your health care provider for advice.

Serious side-effects that you should report to your doctor immediately include:

Those that occur with unknown frequency:

- Drowsiness
- Inability to concentrate
- Dizziness
- Feeling tired
- Headache
- Dry mouth, nose and throat

- Blurred vision
- Difficulty urinating
- Pain or discomfort when urinating
- Tightness of the chest
- Feeling restless
- Diarrhoea
- Constipation
- Nausea
- Vomiting
- Pain in the stomach
- Increased appetite
- An eating disorder called anorexia
- Headache
- Ringing in the ear
- Excitement
- Muscle weakness
- Low blood pressure
- Hallucinations
- Low white blood cell count
- Anaemia.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under

SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8> or by e-mail: drugsafety@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of MEDAZINE S.

5. How to store MEDAZINE S:

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Do not take after the expiry date stated on the packaging material.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MEDAZINE S contains

- The active substance MEDAZINE S is cyclizine hydrochloride 12, 5 mg.
- The other ingredients are: Liquid glucose, purified water, methyl hydroxybenzoate, propyl hydroxybenzoate, saccharine sodium, citric acid monohydrate, sodium citrate, Yellow colour F1523 (Quinolene Yellow CI No. 47005 & Sunset Yellow CI No. 15958), naartjie flavour, sucrose, alcohol 96 %, sorbitol 70 %.

Contains sorbitol 70 %

Contains sugar (Liquid glucose 1,25 mg and sucrose 0,5 mg per 5 mL)

Contains sweetener (saccharine sodium 2,5 mg per 5 mL).

What MEDAZINE S looks like and contents of the pack

MEDAZINE S is a clear yellow syrup with a naartjie flavour.

MEDAZINE S is packed in a round amber glass bottles containing 50 mL, 100 mL, 200 mL and 500 mL syrup, and PET bottles containing 50 mL syrup, packed in unit carton.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Customer Care: 080 222 6662

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.
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